

MINUTES
KENTUCKY BOARD OF PHARMACY
Spindletop Administration Building, Suite 302
2624 Research Park Dr.
Lexington, Kentucky
September 13, 2006

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, Suite 302, 2624 Research Park Dr., Lexington, Kentucky. President Naseman called the meeting to order at 9:11 a.m. A moment of silence was observed in remembrance of September 11, 2001.

Members present: Greg Naseman, Peter Orzali, Mike Leake, Catherine Shely, Sandy Simpson and Patricia Thornbury. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe, Steve Hart and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; Ralph Bouvette, APSC; Chris Killmeier, Walgreens; Susan Gitzinger, KPhA; Jan Gould, Kentucky Retail Federation; Dale Masten, National Association of Chain Drug Stores; Tim Armstrong, Kentucky Board of Pharmacy Advisory Council; Anne Policastri, future board member; Jeff Smith, Agape; Jerry Meyer; Patrick Neblett; Dora Clifton; and Daisy Chai, Joe Hall, and Leslie Yates, University of Kentucky College of Pharmacy PY4 students. Melanie Curtis, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Thornbury, seconded by Mr. Orzali and passed unanimously, the Minutes of July 12, 2006 were adopted as amended.

APPEARANCES: **Jeff Smith/Agape Instruments Service, Incorporated.** Mr. Smith presented a power point presentation on USP Chapter 797 and gave a brief overview of proposed changes.

Jerome Meyer, Jr. Mr. Meyer was sworn in by Melanie Curtis, Court Reporter. Mr. Meyer appeared before the Board to ask for reinstatement of his Kentucky pharmacist's license. Mr. Meyer gave a brief overview of the events that led to the loss of his pharmacist's license and his progress over the last year. After discussion, Mr. Leake moved to deny reinstatement of Jerome Meyer's Kentucky pharmacist's license and required Mr. Meyer to complete 90 AA/NA meetings in 90 days as stipulated in his Agreed Order of Surrender. After completion of the meetings, Mr. Meyer may reappear at the January 2007 Kentucky Board of Pharmacy meeting to request reinstatement. The motion was seconded by Ms. Simpson and passed unanimously.

Patrick Neblett. Mr. Neblett was sworn in by Melanie Curtis, Court Reporter. Mr. Neblett appeared before the Board to ask for reinstatement of his Kentucky pharmacist's license. Mr. Neblett gave a brief overview of the events that led to the loss of his

pharmacist's license. Mr. Neblett voluntarily relinquished his Kentucky pharmacist's license as revoked for a period of time not less than five years and one day due to a felony charge. After a discussion, Mr. Leake moved to reinstate Mr. Neblett's Kentucky pharmacist's license based upon receipt of documentation of completion of federal parole, scheduled to be completed October 22, 2006, and successful completion of the NAPLEX and MPJE, and adopting the same restrictions as the West Virginia Board of Pharmacy: treatment counselor and pastor shall each submit a quarterly report to the Board regarding his progress and compliance with treatment; pharmacist-in-charge of pharmacy where Mr. Neblett is employed shall submit quarterly reports on his job performance, attendance, attitude, and professional demeanor; shall not serve as pharmacist-in-charge at any pharmacy in Kentucky; shall report in writing to the Board any change in residential address or his place of employment or employer, and shall keep the Board advised of his residential and work telephone numbers in writing; if, during the period of restrictions of his license to practice pharmacy, the Board is presented with evidence from any reliable source, proving or tending to prove the Mr. Neblett is not in compliance with one or more terms of this agreement, the Board shall immediately notify Mr. Neblett, in writing, delivered by certified mail, at his last known residential address of the manner in which it is alleged that he has violated the terms of this agreement, suspend the license of Mr. Neblett to practice pharmacy in Kentucky pending an administrative hearing, and schedule a hearing within twenty (20) days of the receipt of the notice; if, by June 28, 2007, the Board has not revoked the license of Mr. Neblett as provided in the prior statement, the above restrictions on the license of Mr. Neblett to practice pharmacy in the Commonwealth of Kentucky, shall expire and shall be deemed to be of no force and affect without any further action by any party; and should proper cause arise or law require, federal and state authorities shall be notified of this settlement via a consent agreement. The motion was seconded by Ms. Thornbury and passed unanimously.

Dora Clifton. Dr. Clifton was sworn in by Melanie Curtis, Court Reporter. Dr. Clifton appeared before the Board to request a modification in her Order on Reinstatement. After discussion, Mr. Orzali moved to modify Dr. Clifton's Order on Reinstatement so that she shall work no more than 42 hours per week or more than 84 hours in any two week period. The motion was seconded by Mr. Leake and passed unanimously.

Tim Armstrong/Kentucky Board of Pharmacy Advisory Council. Mr. Armstrong, chair of the Kentucky Board of Pharmacy Advisory Council, appeared before the Board to receive clarification on the direction the Board would like to pursue in regards to medication errors. After discussion, Dr. Shely moved to have the Advisory Council look at medication errors more closely and offer alternatives, based on literature and research available on medication errors, on how the Board may handle consumer complaints and medication errors. The motion was seconded by Mr. Orzali and passed unanimously.

INTERAGENCY: The United States Drug Enforcement Administration (DEA) is proposing to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II

controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance. DEA is requesting public comment on this proposed rule. Kentucky Revised Statute 218A.180 (1) states, "No prescription for a controlled substance in Schedule II shall be valid after sixty (60) days from the date issued." Drug Enforcement and Professional Practices Branch of the Office of Inspector General investigators and Kentucky Board of Pharmacy, Pharmacy and Drug Inspectors are to communicate with each other on how to handle this situation.

BOARD REPORTS: **President.** 1) President Naseman reported that the PRN Ad Hoc Committee has met for a second time. The Committee is making progress on coordinating the Agreed Orders of Reinstatement and the PRN Agreements and establishing the make-up of the PRN Committee. President Naseman applauded Brian Fingerson for all his work with the Pharmacist Recovery Network. 2) President Naseman stated that the Executive Director Evaluation Committee will meet on the afternoon of October 11, 2006 at 1 p.m. after the PRN Ad Hoc Committee meeting. All Board Members are to review the evaluation and provide feedback to President Naseman.

Board Members. Ms. Thornbury. On August 17, 2006, Ms. Thornbury, Mr. Burleson, and Ms. Lalonde met to review the list of duties for the Board President and President-Elect. Ms. Thornbury moved to include the presented elected officers' job descriptions in the New Board Manual. The motion was seconded by Mr. Leake and passed unanimously. Ms. Lalonde did not want an acknowledgement of her work on the New Member Orientation Manual included in the front of the Manual. The New Board Member Manual Committee recommended a letter from the Kentucky Board of Pharmacy office go to Ms. Lalonde acknowledging her work on the New Board Member Manual.

Ms. Simpson. Ms. Simpson appreciated the opportunity to attend the NABP District III meeting and appreciates the work that the Board does. She will be unable to attend the Kentucky Society of Health System Pharmacists Meeting on November 10, 2006.

Dr. Shely. Dr. Shely would like the Board to review Kentucky Revised Statute 315.120 and consider differentiating between a pharmacist that let his or her license lapse and has an active pharmacist's license in another jurisdiction and a pharmacist without an active pharmacist's license in any jurisdiction.

Board Executive Director. 1) MARS reports included for June and July 2006. 2) Mr. Burleson presented a draft of the Kentucky Board of Pharmacy 2007 calendar. Mr. Orzali moved to accept the calendar. The motion was seconded by Dr. Shely and passed unanimously. 3) The Board received an evaluation of the Board Presentation at the Kentucky Pharmacists Association's Annual Meeting and Convention. 4) The Board directed Mr. Burleson to find out more information including but not limited to cost, disclosure requirements, information to be included and statutory changes needed for the Board of Pharmacy to conduct background checks.

- 5) Mr. Burleson attended the Internet Drug Task Force meeting. There has been good cooperation between several agencies in Kentucky regarding internet pharmacies.
- 6) The Board will have a continuing education program at the Kentucky Society of Health System Pharmacists meeting on November 10, 2006 from 3:20 p.m. to 4:10 p.m. at the Radisson in Lexington.
- 7) Board staff has reviewed the Kentucky Pharmacy Practice Act and has made several suggestions on regulations needing further review and possible revision.
- 8) The Board Retreat will be October 21-22, 2006 at the Louisville Marriott downtown, with the October Board Meeting on Friday, October 20 at 10:00 a.m. at the Marriott. Retreat topics include Wholesalers/Pedigree, Central Fill/Refill, and Compounding /USP 797 and 795.
- 9) Mr. Burleson will present the proposed 2007 travel for the Board at the October 20, 2006 Board meeting.

PRN Chairperson/Brian Fingerson. The Southeast PRN meeting will be held November 10 through 12, 2006 in Atlanta, Georgia. The CAPTASA meeting will be held January 26 and 27, 2007 at the Embassy Suites in Lexington, Kentucky.

CURRENT/PENDING CASES:

Ms. Thornbury moved for acceptance and entry of the proposed Agreed Orders as written. Mr. Leake seconded, and the motion passed unanimously.

Case No. 02-0060; Case No. 05-0036A&B; Case No. 05-0081; Case No. 05-0098A; Case No. 06-0039; Case No. 06-0019

CASE REVIEW COMMITTEE:

Ms. Thornbury moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Shely seconded, and the motion passed unanimously.

Case No. 05-0038. REVISIT. Pharmacist allegedly had action taken against Indiana pharmacist's license due to impairment issues. **New Information:** Final Order from Indiana received. Kentucky pharmacist's license has lapsed. Alleged violation of law: KRS 351.121(2). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0030A. Pharmacy permit holder allegedly committed a medication error. A complaint received from a doctor alleged that she prescribed Prednisone 10mg # 43. The prescription label directions were allegedly printed incorrectly causing the patient to take more of the medication than prescribed. Alleged violations of law: KRS 315.121(1)(a) and (2)(d). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 06-0030B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A complaint received from a doctor alleged that she prescribed Prednisone 10mg #43. The prescription label directions were allegedly printed incorrectly causing the patient to take more of the medication than prescribed. Alleged violations of law: KRS 315.121(1)(a) and (2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0044. Pharmacist allegedly refilled a prescription for several months without authorization from the physician. Alleged violation of law: 201 KAR 2:185, section 1(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0045A. Pharmacy permit holder allegedly engaged in unprofessional and unethical conduct by overcharging a patient for a prescription after billing the patient's insurance. Alleged violations of law: KRS 315-121(1)(a) and (2)(h). CRC Recommendation: Case is dismissed.

Case No. 06-0045B. Pharmacist allegedly engaged in unprofessional and unethical conduct by overcharging a patient for a prescription after billing the patient's insurance. Alleged violations of law: KRS 315-121(1)(a) and (2)(h). CRC Recommendation: Case is dismissed.

Case No. 06-0047A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. Prescription allegedly filled with the wrong prescriber. Alleged violation of law: KRS 217.065(1). CRC Recommendation: Case is dismissed.

Case No. 06-0047B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Prescription allegedly filled with the wrong prescriber. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: Case is dismissed.

Case No. 06-0048A. Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. Patient received Zebeta 10mg instead of Zetia 10mg. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 06-0048B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Patient received Zebeta 10mg instead of Zetia 10mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through

an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0061. Pharmacist was allegedly in possession of Tamiflu and Nasonex without being labeled and did not have a prescription for these items. Pharmacist allegedly stole numerous OTC items from a pharmacy. Pharmacist allegedly stole various required pharmacy equipment items from a pharmacy while working. Pharmacist was allegedly seen drinking Prednisolone from a 4 oz. bottle while working. Alleged violation of law: KRS 315.121(2). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0063A. Pharmacy permit holder allegedly sold a misbranded drug as a result of a medication error. This pharmacy is closed and the details of the medication error could not be tracked. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 06-0063B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. This pharmacist is a floater and did remember making an error, but he could not remember at which pharmacy he was working when the error occurred. He did file the error with his insurance company. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0066. Special limited medical gas permit holder allegedly stored legend drug in an unlicensed location. Alleged violation of law: KRS 217.182(7). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0067A. Manufacturer permit holder allegedly opened in a new location and already placed legend drugs (medical oxygen) in the new location prior to inspection and the issuance of a permit for that location. Alleged violations of law: KRS 315.035(5) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0067B. Special medical gas permit holder allegedly opened in a new location and already placed legend drugs (medical oxygen) in the new location prior to

inspection and the issuance of a permit for that location. Alleged violations of law: KRS 315.035(5) and 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of hearing.

Case No. 06-0067C. PIC responsible for a manufacturer permit and special medical gas permit allegedly allowed the two permits to open in a new location and already place legend drugs (medical oxygen) in the new location prior to inspection and the issuance of a permit for those locations. Alleged violation of law: 201 KAR 2:225. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of hearing.

Case No. 06-0070. Special medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0071. Special medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0072. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0073. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0074. Pharmacy permit holder allegedly failed to renew permit in a timely and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0075. Pharmacy permit holder allegedly failed to renew permit in a timely and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0077. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0078. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0079. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035(1) and (4). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0080. Pharmacist allegedly violated her KYPRN Agreement with a positive drug screening, failed to timely submit meeting logs and did not notify PRN of prescribed medications. Alleged violation of law: KRS 351.121(2). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0082. Special limited medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violations of Law: KRS 315.035 (1) and (4) and 201 KAR 2:225.

CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0083. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035 (1) and (4). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0084. Pharmacy permit holder allegedly failed to renew permit in a timely manner and did not continue to operate as a pharmacy. Alleged violations of law: KRS 315.035 (1) and (4). **CRC Recommendation:** Case is dismissed.

Case No. 06-0085. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035 (1) and (4). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0086. Pharmacy permit holder allegedly failed to renew permit in a timely manner and did not continue to operate as a pharmacy. Alleged violations of law: KRS 315.035 (1) and (4). **CRC Recommendation:** Case is dismissed.

Case No. 06-0087. Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. Alleged violations of law: KRS 315.035 (1) and (4). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0088A. Special medical gas pharmacy permit holder allegedly opened a new location and had already placed legend drugs (medical oxygen) in the new location prior to an inspection. Alleged violations of law: KRS 315.035(5) and 201 KAR 2:225. **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0088B. PIC of special medical gas pharmacy allegedly allowed the special medical gas pharmacy to open a new location and already have in place legend drugs (medical oxygen) in the new location prior to an inspection. Alleged violations of law: KRS 315.035(5) and 201 KAR 2:225. **CRC Recommendation:** There is sufficient

evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0089A. Special medical gas pharmacy permit holder allegedly failed to complete quarterly inspections in a timely manner and failed to track cylinders by lot number. Alleged violations of law: 201 KAR 2:225 Sec 2(1)(b) and 21 CFR. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 06-0089B. Consultant pharmacist allegedly failed to complete quarterly inspections in a timely manner and failed to track cylinders by lot number. Alleged violations of law: 201 KAR 2:225 Sec 2(1)(b) and 21 CFR. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 06-0090A. Special medical gas pharmacy permit holder allegedly failed to maintain current prescriptions for oxygen on file at facility, failed to conduct quarterly inspections, failed to properly label oxygen cylinders with the name/address of the dispensing med gas pharmacy, failed to have in place a tracking mechanism for dispensed cylinders, failed to properly secure oxygen cylinders against falling and legend pharmaceuticals (not oxygen) were discovered on the premises. Alleged violations of law: 201 KAR 2:225; 29 CFR 1926.350; 21 CFR 211.10, 150, 610.61; KRS 217.065; 315.035. **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 06-0090B. Consultant pharmacist allegedly failed to maintain current prescriptions for oxygen on file at facility, failed to conduct quarterly inspections, failed to properly label oxygen cylinders with the name/address of the dispensing med gas pharmacy, failed to have in place a tracking mechanism for dispensed cylinders, failed to properly secure oxygen cylinders against falling and allowed other legend pharmaceuticals (not oxygen) on the premises. Alleged violations of law: 201 KAR 2:225; 29 CFR 1926.350; 21 CFR 211.10, 150, 610.61; KRS 217.065; 315.035. **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

RECIPROCITY/RELICENSURE/INTERNSHIP:

Debra Montoya. Ms. Montoya was requesting reinstatement of her Kentucky pharmacist's license which lapsed on March 1, 2001. She currently does not hold an active pharmacist's license in any state. Mr. Leake moved to inform Ms. Montoya that current Kentucky statute KRS 315.120 (3) states that she must satisfy the continuing education requirements, pass both the NAPLEX and MPJE, and pay the renewal and penalty fees in order to get her Kentucky pharmacist's license reinstated. Ms. Thornbury seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATIONS:

Kentucky Board of Physical Therapy. The Kentucky Board of Physical Therapy was requesting that physical therapists be allowed to use "community jars (stock containers)/community solutions" of compounded medications in physical therapy treatment. Dr. Shely moved for the Executive Director to send a response to the Kentucky Board of Physical Therapy that this is not possible under current law because all prescriptions must be patient specific. Ms. Thornbury seconded, and the motion passed unanimously.

Mike Lusk. Mr. Lusk was requesting permission to be dual pharmacist-in-charge of Betsy Layne Pharmacy and Oxygen Plus Pharmacy and that the pharmacies be allowed to share the necessary equipment including refrigerator and sink, and reference material. Ms. Thornbury moved to allow Mr. Lusk to be dual pharmacist-in-charge of Betsy Layne Pharmacy and Oxygen Plus Pharmacy and to allow the pharmacies to share equipment and reference material. Ms. Simpson seconded, and the motion passed unanimously.

NABP: Mr. Naseman and Mr. Burleson submitted their names to be on the NABP Internet Pharmacy Committee in the event that NABP revisits this issue.

CONTINUING EDUCATION: Ms. Thornbury moved to accept the continuing education programs 06-35 through 06-51 as recommended. Dr. Shely seconded, and the motion passed unanimously.

OLD BUSINESS:

A. Central Fill/Refill Processing Regulation. Information on Central Fill/Refill Pharmacies included for discussion at the Board Retreat.

1. Central Refill Tour. The Board members and staff will tour the Central Refill Pharmacy at 8 a.m. on October 20, 2006, before the Board meeting.

B. Wholesaler/Pedigree. Mr. Burleson will gather information on this topic for discussion at the Board Retreat.

C. USP 797 and 795/Compounding. Mr. Burleson and Mr. Leake will gather information on this topic for the Board Retreat.

ADJOURNMENT: On motion by Mr. Orzali, seconded by Dr. Shely, and passed unanimously, President Naseman adjourned the meeting at 3:10 p.m. The next regularly scheduled Board meeting is scheduled to begin at 10:00 a.m. on October 20, 2006 at the Downtown Marriott in Louisville, Kentucky.

Michael Burleson, Executive Director

